more than 2 percent. When reconstituted as directed in the labeling, its pH is not less than 3.0 and not more than 6.0. The cephalexin used conforms to the standards prescribed by § 442.27(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The cephalexin used in making the batch for potency, moisture, pH, absorptivity, identity, and crystallinity.

(*b*) The batch for potency, moisture, and pH.

(ii) Samples required:

(*a*) The cephalexin used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of six immediate containers.

(b) *Tests and methods of assay*—(1) *Potency.* Use either of the following methods; however, the results obtained from the microbiological agar diffusion assay shall be conclusive.

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Reconstitute the sample as directed in the labeling. Transfer an accurately measured representative portion of the suspension into an appropriate-sized volumetric flask and dilute to volume with 1-percent potassium phosphate buffer, pH 6.0 (solution 1). Further dilute an aliquot of this solution with solution 1 to the reference concentration of 20.0 micrograms of cephalexin per milliliter (estimated).

(ii) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, preparing the sample as follows: Reconstitute the sample as directed in the labeling. Transfer an accurately measured representative portion to a volumetric flask and bring to volume with distilled water. Further dilute an aliquot of this solution with distilled water to the prescribed concentration of cephalexin.

NOTE: The 10 milliliters of 0.01*N* iodine must be added within 20 seconds after the addition of the 2.0 milliliters of 1.2*N* hydrochloric acid, and the assay should be completed within 1 hour after the sample and standard are first put into solution.

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(3) *pH.* Proceed as directed in § 436.202 of this chapter, using the drug reconstituted as directed in the labeling.

[39 FR 19040, May 30, 1974, as amended at 45 FR 16472, Mar. 14, 1980; 50 FR 19919, May 13, 1985]

§ 442.128 Cephalexin hydrochloride monohydrate tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Cephalexin hydrochloride monohydrate tablets are composed of cephalexin hydrochloride monohydrate and one or more suitable and harmless lubricants, colorings and coating substances. Each tablet contains cephalexin hydrochloride monohydrate equivalent to 250 milligrams, 333 milligrams or 500 milligrams of cephalexin. Its cephalexin content is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of cephalexin that it is represented to contain. Its moisture content is not more than 8.0 percent. The tablets pass the dissolution test. It passes the identity test. The cephalexin hydrochloride monohydrate used conforms to the standards prescribed by § 442.28(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(A) The cephalexin hydrochloride monohydrate used in making the batch for cephalexin potency, moisture, pH, identity, and crystallinity.

(B) The batch for cephalexin content, moisture, dissolution, and identity.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research.

(A) The cephalexin hydrochloride monohydrate used in making the batch: 10 packages, each containing approximately 500 milligrams.

(B) The batch: A minimum of 36 tablets.

(b) *Tests and methods of assay*—(1) *Cephalexin content.* Proceed as directed in §442.140c(b)(1)(ii), except that ''cephalexin'' is substituted at each occurrence of ''cephradine''.

(2) *Moisture.* Proceed as directed in §436.201 of this chapter.

(3) *Dissolution.* Proceed as directed in §436.215 of this chapter. The quantity *Q* (the amount of cephalexin dissolved) is not less than 75 percent at 45 minutes.

(4) *Identity.* Proceed as directed in §436.367 of this chapter.

[54 FR 48860, Nov. 28, 1989]

§442.140a Cephradine for oral suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Cephradine for oral suspension is cephradine with one or more suitable and harmless diluents, buffer substances, colorings, and flavorings. When reconstituted as directed in the labeling, each milliliter contains 25 milligrams or 50 milligrams of cephradine. Its potency is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of cephradine that it is represented to contain. Its moisture content is not more than 1.5 percent. When reconstituted as directed in the labeling, its pH is not less than 3.5 and not more than 6.0. The cephradine used conforms to the standards prescribed by §442.40(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of §432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The cephradine used in making the batch for potency, moisture, pH, cephalexin content, identity, and crystallinity.

(*b*) The batch for potency, moisture, and pH.

(ii) Samples required:

(*a*) The cephradine used in making the batch: 10 packages, each containing 500 milligrams.

(*b*) The batch: A minimum of six immediate containers.

(b) *Tests and methods of assay*—(1) *Potency.* Use either of the following methods; however, the results obtained from the microbiological agar diffusion assay shall be conclusive.

(i) *Microbiological agar diffusion assay.* Proceed as directed in §436.105 of this chapter, preparing the sample for assay as follows: Reconstitute the sample as directed in the labeling. Transfer an accurately measured representative portion of the suspension into an appropriate-sized volumetric flask and dilute to volume with 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to obtain a stock solution of convenient concentration. Further dilute an aliquot of the stock solution with solution 1 to the reference concentration of 10.0 micrograms of cephradine per milliliter (estimated).

(ii) *Hydroxylamine colorimetric assay.* Proceed as directed in §442.40(b)(1)(ii) of this chapter, preparing the sample as follows: Reconstitute the sample as directed in the labeling. Transfer an accurately measured representative portion to a volumetric flask and bring to volume with distilled water. Further dilute an aliquot of this solution with distilled water to 1 milligram of cephradine per milliliter (estimated).

(2) *Moisture.* Proceed as directed in §436.201 of this chapter.

(3) *pH.* Proceed as directed in §436.202 of this chapter, using the drug reconstituted as directed in the labeling.

[40 FR 26272, June 23, 1975, as amended at 45 FR 16476, Mar. 14, 1980; 50 FR 19919, May 13, 1985]

§442.140b Cephradine capsules.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Cephradine capsules are composed of cephradine and one or more suitable and harmless lubricants and diluents enclosed in a gelatin capsule. Each capsule contains 250 milligrams or 500 milligrams of cephradine. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of cephradine that it is represented to contain. Its loss on drying is not more than 7.0 percent. The cephradine used conforms to the standards prescribed by §442.40(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of §432.5 of this chapter.